

DOCKET NO: WYTH0011-100 (AM100155)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Inventor application of:	Benjamin et al.	Group Art Unit:	1617
		Examiner:	Shobha Kantamneni
Serial No.:	09/896,226	Confirmation No.:	9422
Filed:	June 29, 2001	Docket No.:	WYTH0011-100 (AM100155)
For:	PHARMACEUTICAL COMPOSITION OF ESTROGENIC AGENTS		
Customer No.:	35139		

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

VIA EXPRESS MAIL LABEL NO: EV772 143 524US

DATE SENT: August 7, 2006

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08B, formerly known as PTO Form 1449, submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made.

This Supplemental Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.

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- ☐ **before** the mailing date of a first Office Action on the merits.
- ☐ **before** the mailing date of a first Office Action on the merits with the filing of a Request for Continued Examination under § 1.114.
- ☒ **after** the mailing date of a first Office Action on the merits or after the filing of a Request for Continued Examination under § 1.114, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☒ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☒ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with the ☐ first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), and the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p).
- ☒ Copies of the references listed on the attached PTO Form SB/08B, formerly known as PTO Form 1449, are enclosed.

EXCEPT THAT:

- ☐ In view of the voluminous nature of references, and the likelihood that these reference are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) _____ for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☒ The undersigned attorney hereby states that each item information contained in the Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Fees

- ☐ No Information Disclosure Statement Fee is owed by the applicant(s).
- ☒ The Supplemental Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☒ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,



Michael A. Patané
Reg. No. 42,982

Dated: August 7, 2006

COZEN O'CONNOR, P.C.
1900 Market Street, 5th Floor
Philadelphia, PA 19103-3508
215-665-6966 - Telephone
215-701-2100 - Facsimile



PTO/SB/08b(08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449B/PTO

**SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/896,226
Filing Date	June 29, 2001
First Named Inventor	Eric J. Benjamin et al.
Art Unit	1617
Examiner Name	Shobha Kantamneni
Attorney Docket Number	WYTH0011 100 (AM100455)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	22	Lachman et al., <i>The Theory and Practice of Industrial Pharmacy</i> (1970) pp. 689-690.	
	23	Lesson et al., "Stability of tetracycline and riboflavin," <i>J of Pharmaceutical Sciences</i> (1969) 58(3):355-357.	
	24	Liebrman et al., <i>Pharmaceutical Dosage Forms - Tablets</i> (1980) 1:86-88.	
	25	Liebrman et al., <i>Pharmaceutical Dosage Forms - Tablets</i> (1980) 1:72-83.	
	26	Wells "Pharmaceutical preformulation: the Physicochemical Properties of Drug Substances, (1988) p. 171.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.